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# **EXHIBIT 6**

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC.	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 01-1997
	)	
TYCO HEALTHCARE GROUP,	)	
ET AL.	)	
Defendants.	)	

MEMORANDUM ORDER

GARY L. LANCASTER,  
District Judge.

July 16, 2004

This is an action in patent infringement. Plaintiff, Medrad, Inc. ("Medrad") alleges that defendants, Tyco Healthcare Group, et al. ("Tyco") infringed U.S. Patent No. Re. 37, 602 ("'602") entitled "Patient Infusion System For Use With MRI" when it licensed the Optistar MR Contrast Delivery System ("the Optistar injector"). Tyco counters that its product (the Optistar injector) does not read on or infringe the '602 patent, and that the '602 patent is invalid. Presently before the court is the Markman patent claim construction hearing pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996).

**THE PATENT**

The '602 patent discloses a patient infusion system for use with Magnetic Resonance Imaging (MRI). The infusion apparatus, which is located in the MRI scan room, contains two injectors

through which contrast solution and saline are injected into the patient based upon perimeters set by a technician who operates the system from a console outside the MRI scan room. The illuminating contrast solution then travels to the organ being scanned and enhances the visual images captured by the MRI scan. The patient infusion system decreases interference between the magnetic field used to produce MRI scans and other magnetic fields created by ancillary equipment, resulting in clearer MRI images. Moreover, the use of the contrast delivery system greatly improves a radiologist's ability to read the MRI scan, resulting in more accurate diagnoses.

Of the 44 claims offered in this patent, Claims Nos. 9 and 25 contain all of the disputed terms. Therefore, I will focus my analysis on the following items which are bolded and italicized.

**CONTESTED CLAIMS WITH DISPUTED TERMS/PHRASES BOLDED**

**Claim 9:**

A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

- a) a room shielded from electromagnetic interference, which includes a viewing window;
- b) a *system controller* external to the shielded room;

c) a patient infusion apparatus within the shielded room and including *infusion apparatus control means for controlling an infusion operation*; and,

d) a *communicating control link* between the system controller and the infusion apparatus control means, *the control link adapted to be substantially non-reactive with the magnetic field of the imaging system.*

**Claim 25:**

A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:

An infusion apparatus positioned within a room shielded from electromagnetic interference, the infusion apparatus comprising an injection adapted to accommodate at least two syringes mounted thereon for injecting fluid into a patient during a magnetic resonance imaging procedure, *the at least two syringes operably engaged with at least one drive mechanism of the injection*; and

a system controller positioned external to the shielded room and in communication with the infusion apparatus for controlling the operation thereof.

## PRINCIPLES OF PATENT CLAIM CONSTRUCTION

### I. General Tenets

Patent claim construction is a matter of law for the court. Markman, 52 F.3d at 979. A court begins its analysis of a patent claim by first looking to the language the inventors used in their claims to define the scope of their invention. See John Worldwide Assoc. Inc. v. Zebco Corp. 175 F.3d 985, 989 (Fed. Cir. 1999). This language is given an ordinary and accustomed meaning as understood by those of ordinary skill in the art. Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 955 (Fed. Cir. 2000) (citing Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996)); and Markman, 52 F.3d at 980; Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1353 (Fed. Cir. 2000) (citing York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996)). Dictionaries, encyclopedias and treatises available at the time the patent is issued are reliable sources of information on the established means that would have been attributed to the terms of the claim by those skilled in the art. As the Federal Circuit recent held, dictionaries, encyclopedias and treatises are not extrinsic evidence and are a good starting point for claim construction. Texas Digital Systems Inc. v. Telegenix, 308 F.3d 1193, 1202 (Fed. Cir. 2002).

The remainder of the intrinsic record, the patent specification and prosecution history, is next examined to resolve ambiguities existing after considering the claim language itself and to determine whether the inventors intended to use the claim language differently from that commonly understood in the art. Markman, 52 F.3d at 979, 980; see, e.g., Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 705 (Fed. Cir. 1997); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The court must then review the specification, of which the claims are a part. See Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 979. Claims should be interpreted consistently with the specification, which provides content for the proper construction of the claims because it explains the nature of the patentee's invention. See Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). The prosecution history should also be considered. The public has a right to rely on statements made by the patent applicant or his attorney during prosecution that define the scope of the claims. See Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997).

The Federal Circuit has cautioned, however, against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in the specification. See, e.g., Ekchian, 104 F.3d at 1303; Intervet America, Inc. v. Kee-Vet Laboratories,

Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("[L]imitations appearing in the specification will not be read into claims, and . . . interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'" ) (citation omitted).

Section 112 of the Patent Act requires that a patent specification describe an invention and do so in sufficient detail that one skilled in the art can reasonably conclude that, as of the filing date, the inventors were in possession of the claimed invention. See Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). The written description requirement "is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure . . . . Rather, it is a question whether the application necessarily discloses that particular device." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997) (citations omitted). The specification must sufficiently describe the claimed invention such that persons skilled in the art can discern that the inventor has in fact invented what has been claimed. See Johnson Worldwide Assocs. Inc., v. Zebco Corp., 175 F.3d 985, 993 (Fed. Cir. 1999).

In this regard, the common method employed by defendant in developing its proposed claim construction was to focus, in the

first instance, on either the preferred embodiments set forth in the specifications or to the specifics of the commercial product produced by plaintiff--not to the language of the claim. Indeed, at the Markman hearing defense counsel seldom even made mention of the actual claim language but rather consistently focused the court's attention to either the patent specifications or the manner in which the competing products were commercially produced. This may be proper advocacy, but it is not the appropriate method of claim construction. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("First and foremost, the analytical focus of claim construction must begin, and remain centered, on the language of the claims themselves").

#### THE COURT'S PATENT CLAIM CONSTRUCTION

##### I. System Controller:

Claim 9(a): a *system controller* external to the shielded room

Claim 25: a *system controller* positioned external to the shielded room and in communication with the infusion apparatus for controlling the operation thereof.

A "controller" is defined in Webster's Third New International Dictionary as "a hand-operated or automatic mechanism used to regulate or guide the operation of a machine or an apparatus or a system (as a steam shovel, a radio, a heating

system)." It also defines "system" as "a complex unity formed of many often diverse parts subject to a common plan or serving a common purpose." We see nothing in the patent specifications or history that indicates that these terms should not be given their common ordinary meanings. Therefore, we construe a **system controller** as a hand-operated or automatic device used to regulate or guide the operation of a MRI patient infusion system.

**II. infusion apparatus control means for controlling an infusion operation:**

Claim 9(c): a patient infusion apparatus within the shielded room and including **infusion apparatus control means for controlling an infusion operation**;

The parties dispute the meaning of the phrase "infusion apparatus control means for controlling an infusion operation," as written in claim 9, subpart c. Both parties agree, however, that the court should employ the "means plus function" format as dictated by 35 U.S.C. § 112, ¶ 6.

The "means plus function" is a format for stating patent claims. Section 112 of Title 35 provides that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, materials, or acts described in the specification and equivalent thereof." 35

U.S.C. § 112. "When interpreting a claim written in the 'means-plus-function format' the court must construe the functional language of the claim 'to cover the corresponding structure, materials, or acts described in the specification and equivalents thereof.'" Sightsound.Com Inc. v. N2K, Inc., 185 F.Supp.2d. 445, 456 (W.D. Pa. 2002) (quoting 35 U.S.C. § 112). "The patentee, however, must describe in the specification some structure which performs the specified function." Id.

The means plus function format requires the court to first identify the function recited in the claims, and then identify the structure disclosed in the patent to perform that function. Asyst Technologies, Inc. v. Empak, Inc., 268 F.3d 1364, 1370 (Fed. Cir. 2001). Here, the function element of this phrase is "for controlling an infusion operation."

The next step is to determine the structure disclosed in the patent to perform the function of controlling an infusion operation. Column 4:8-10 of the specification states: "The injection control unit 30 also incorporates control circuitry which controls electric motors 35, 36 which are also located within the injection control unit." Based upon this language in the specification, Medrad construes the phrase to mean "control circuitry or equivalent structure for controlling an infusion operation."

Tyco, however, asserts that based upon the "means plus function" format, the phrase "infusion apparatus control means for controlling an infusion operation" should be construed as "an injection control unit that is physically separated from the infusion apparatus by as great a distance as possible and that includes control circuitry in the injection control unit, electric motors also in the injector control unit, and non-rigid operating drives connecting the motors to an infusion apparatus for controlling an infusion operation."

After reviewing the parties differing constructions, the court agrees with Medrad that the claim terms should not be construed to include the limitations added by Tyco including electric motors and non-rigid drive shafts. "Control circuitry or the equivalent" is the means through which the function of "controlling an infusion operation" is carried out. In other words, what "controls the infusion operation" is the control circuitry, as was stated in the specification.

During the Markman hearing the court analogized the process to the brakes in a car. If one claimed a "means of stopping a car" under the means-function analysis, it would be the brake shoe compressing against the wheel that performs the function of stopping the car, not the driver depressing the brake pedal. The driver depressing the brake pedal enables the brake shoe to operate as intended. The driver's foot and the pedal are

necessary to stop the car; however, they are not a part of the car's "brakes." So to here, the infusion operation as claimed by plaintiff is not performed by the electric motors, the drive shaft or the spacing of the motors. (Motors spacing actually serves the function of non-interference with the magnetic field. The spacing does not affect the infusion operation.) The motors and the non-rigid flexible drive shafts enable the control circuitry to work but they do not "control" the infusion operation. Instead, the infusion operation is controlled by the control circuitry.

In summary, the Federal Circuit teaches that "it is not necessary to claim in a patent every device required to enable the invention to be used." Hughes Aircraft Co. v. United States, 640 F.2d 1193, 1197 (Fed. Cir. 1980). The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended. We therefore disagree with the defendant that the electric motors and non-rigid operating drives should be regarded as part of the structure corresponding to the functions set forth in the claim.

Accordingly, the phrase "infusion apparatus control means for controlling an infusion operation" is construed to mean "control circuitry or equivalent structure for controlling an

infusion operation." This language is based upon the specification set forth in Column 4:8-10.

III. *Communications/Communicating control link..adapted to be substantially non-reactive with the magnetic field of the imaging system.*

Claim 9d) a *communicating control link* between the system controller and the infusion apparatus control means, *the control link adapted to be substantially non-reactive with the magnetic field of the imaging system.* The communication link is the component for sending instruction signals from the operator in the control room to the injection head unit in the scan room.

The parties vigorously dispute the above-mentioned phrase as contained in claim 9, subpart d. Medrad asserts that consistent with the ordinary meaning of the terms, the phrase should be construed to mean "a piece or complex of apparatus for imparting or transmitting control information...having minimal or no influence or effect on, and being minimally or not influenced by forces due to the MRI imaging system."

Tyco, on the other hand, seeks to limit the construction to mean "an infrared or optical system that does not create electromagnetic radiation for imparting or transmitting information for controlling the operation of the patient infusion system and excluding hardwired electrical cables that breach the electromagnetic shield. The magnetic field is the static magnetic field  $B_0$ ."

After construing the ordinary meaning of the claim terms with the help of intrinsic aids including the dictionary, as well as referencing the claims themselves (specifically contrasting to claims 8 and 31), this court finds Medrad's construction to be accurate. Nonetheless, the court will address each disputed claim term in claim 9, subpart d and the differing proposed constructions.

A) **Communications/Communicating Control Link Adapted to be Substantially Non-Reactive:**

Defendant contends that this claim should be limited to consist of either infrared technology or fiberoptic technology for transmitting the information. Further, that the claim be construed as expressly excluding hard-wired electrical cables as the transmitting technology. The court rejects defendant's proposed construction for several reasons.

First, there is nothing in the language of the claim itself that suggests such a limitation:

Second, claim 9 is a broad claim. The more narrow claims that are dependent on claim 9 are claims 11, in which plaintiff claims a communication link using infrared technology, and claim 22, in which plaintiff claims a communication link comprised of fiberoptic technology. There is a presumption in patent claim construction that where a limitation that is sought to be read into an independent claim already appears in a dependent claim, the doctrine of claim differentiation applies. Liebel-Flarsheim

Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004). The doctrine of claim differentiation provides that because each claim is presumed to have a different scope, it is presumptively unreasonable to construe one claim so as to render another claim superfluous. Beachcombers, Int'l v. WildeWood Creative Prod., Inc., 31 F.3d 1154, 1162 (Fed.Cir.1994); Intel Corp. v. Broadcom Corp., 172 F.Supp.2d. 478, 496 (D.Del.2001) ("In interpreting claims, it is improper for courts to read into an independent claim a limitation that is explicitly set forth in another [dependent] claim"); see also, Ecolab Inc. V. Paraclipse, Inc., 285 F.3d 1362, 1376 (Fed. Cir. 2001) (noting that this presumption is strengthened when there is a dispute over whether "a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims").

Under the doctrine of claim differentiation, reading the limitation of the specific of infrared or fiber optic into claim 9 would render dependent claims 11 and 22 superfluous, which is presumptively unreasonable. Beachcombers, 31 F.3d at 1162. This presumption is heightened here, because the technology limitation is the only meaningful difference between claim 9 and claims 11 and 22. While the court realizes that claim differentiation is a guide and not a strict rule, the guidance provided by this doctrine strongly supports the court's construction.

Nor are we persuaded by defendants' referral to the specifications. Although the specifications discuss both

infrared and fiberoptic technology in creating the communications link, see column 2 line 66 through column 3 line 12, the inventors expressly referred to these technologies as "the preferred embodiment" not as a limitation of the invention. As stated previously, the Federal Circuit has repeatedly cautioned against limiting the scope of a claim to the preferred embodiment or to specific examples that appear in the specifications. The court further cautions that "interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." Intervet Am. Inc. v. Kee-vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989).

Thus, for all these reasons the court construes the communications link as not being limited to fiberoptic or infrared technology. Furthermore, the court finds that the communications link does not exclude hardwired technology.

**B) Magnetic Field of the Imaging System:**

Defendants seek to construe "the magnetic field of the imaging system" as being limited to the static magnetic field "B<sub>0</sub>". The parties don't dispute, indeed, they agree, that in order for MRI technology to work, an interplay of three magnetic fields is necessary: the patient's magnetic field, "M"; the static magnetic field created by the magnet contained in MRI

machine "B<sub>0</sub>"; and the oscillating magnetic field, B<sub>1</sub>. Defendants' proposed construction would limit plaintiff's claim to an invention in which the control link is substantially non-reactive with only one field, "B<sub>0</sub>" and by negative inference, could interfere with the other two necessary magnetic fields. Thus, defendants' proposed construction would have plaintiff claim an invention that probably would not work.

Defendants have failed to direct the court to any language in this claim, in the specifications, or in the patent history that supports such a limitation.

Moreover, I find that one who is skilled in the art of MRI technology would understand that the term "magnetic field of the imaging system" includes all three magnetic fields necessary to produce an image. Again, there seems to be no basis for defendants to assert this limitation in this claim.

IV. *the at least two syringes operably engaged with at least one drive mechanism of the injection:*

Claim 25) A patient infusion system for use with a magnetic resonance imaging system, the patient infusion system comprising:


An infusion apparatus positioned within a room shielded from electromagnetic interference, the infusion apparatus comprising an injection

adapted to accommodate at least two syringes mounted thereon for injecting fluid into a patient during a magnetic resonance imaging procedure, *the at least two syringes operably engaged with at least one drive mechanism of the injection;*

Finally, the parties dispute the meaning of the above highlighted phrase as contained in claim 25. Medrad contends that the phrase should be construed to mean "two or more syringes each contacting, interlocking or meshing with at least one drive mechanism for use on the injector." Again, Medrad bases its proposed construction on the dictionary definitions of "operably" and "engaged." "Operably" means "fit, possible, or desirable to use, and "engaged" means "to come in contact or interlock with: mesh [the teeth of one gear wheel engaging those of another to transmit power;] also: to cause (parts) to engage [the gears, the slowly let in your clutch.]" Defendants' proposed construction tracks the language of the claim itself but adds a prefix: "It is possible for the at least two syringes to mesh with at least one drive mechanism of the injector." Defendants have failed to point to anything in the language of the claim, the specifications, or the patent history that warrants prefixing the claim with "It is possible." We reject defendants' construction

of the claim term and adopt plaintiff's because its construction is consistent with the ordinary meanings of the terms.

BY THE COURT:

  
\_\_\_\_\_, J.

Dated: July 16, 2004

cc: All Counsel of Record

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC.	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 01-1997
	)	
TYCO HEALTHCARE GROUP,	)	
ET AL.	)	
Defendants.	)	

MEMORANDUM ORDER

GARY L. LANCASTER,  
District Judge.

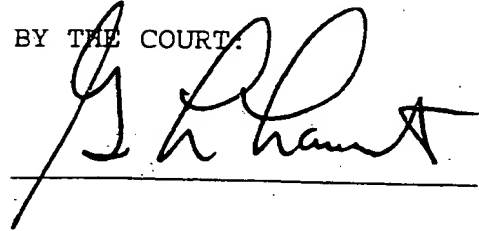
August 5, 2004

This is an action in patent infringement. On July 16, 2004, this court construed what the court believed were all the disputed claims pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Plaintiff, Medrad, Inc. ("Medrad") requests "clarification" of the court's July 16, 2004 order. We read the request, however, as asking the court to construe the additional claim term, "injector control unit."

In Webster's Third New International Dictionary, a "unit" is defined as "a piece or complex of apparatus serving to perform one particular function." A "control" is defined as "a hand-operated or automatic mechanism to regulate or guide the operation of a machine or an apparatus or system." This court construes the term "injector control unit," consistent with

ordinary meaning as "a piece or complex of apparatus that regulates or guides the operation of an MRI contrast injector."

BY THE COURT:

  
\_\_\_\_\_, J.

Dated: August 5, 2004

cc: All Counsel of Record

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